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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,095	04/12/2001	Yoshihiro Kawaoka	800.026US1	5332

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EXAMINER
MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
1636	10

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,095	KAWAOKA, YOSHIHIRO	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/4/03, 6/12/03* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *2-4,7,8,10-24 and 27-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,9,25,26 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's election with traverse of species isolated and purified recombinant influenza virus comprising a mutant M2 protein which lacks or has reduced activity relative to wild type M2, wherein the mutation is a deletion in the transmembrane domain and wherein the mutation does not alter the in vitro replication of the virus but is associated with attenuation of the virus in vivo, claims 1, 5-6, 9, 25-26, and 31 in Paper No. 14, filed 6/12/03 is acknowledged. The traversal is on the ground(s) that a generic claim and subgeneric claims drawn to a deletion or an amino acid substitution or comprising a chimeric protein have already been searched and examined. This is not found persuasive because the examination of the original generic and subgeneric claims already was approaching too burdensome levels, but was able to be completed. However, the applicant's amendment resulted in the addition of about 13 new specific species previously unexamined which would have to be searched independently of each other because art applicable to one

species is not necessarily applicable to the other species, especially since the previously cited art is no longer applicable due to the applicant's additional limitation to the claims. It became simply too burdensome to properly search and examine all of the old and new species due to the extremely limited time that the examiner is allocated by the Patent Office. Thus, it is proper to further restrict the claims by requiring an election of species, as permitted under the Patent Office's rules.

It is also argued that the requirement to elect a species is also traversed on the basis that the disclosed species have a disclosed relationship, the mutations are in the transmembrane region and yield a virus that is attenuated in vivo but not in vitro. This argument is not persuasive because having a disclosed relationship (both structurally and functionally) is the essence of the concept of species. The argument simply reinforces what the examiner is already indicating: that the different mutants are species of each other. Because the claims now have too many species to properly search and examine, an election of species is required. If the applicant is arguing that one species make obvious the other species then the applicant should have clearly stated that and the examination of all species would have been carried out accordingly. However,

for example, if the applicant is not willing to admit that art describing a mutant having an alanine to proline substitution at residue 30 of M2 renders obvious a deletion of residues 29 to 31 of M2, then the applicant should understand the need for election of species because there are now over 13 different species, which would potentially require 13 or more art searches and art rejections assuming art is found in each case. That would be extremely burdensome and undue.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 2-4, 7-8, 10-24, and 27-30 are drawn to an invention and/or species nonelected with traverse in Paper Nos. 9 and 14. A complete reply to the final rejection must include cancelation of nonelected claims and/or subject matter or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The oath/declaration specifically indicates that no claim for priority for the benefit under 35 USC 119(e) is being made at the time. This is incorrect because at the time of the signing of and the filing of the oath/declaration a claim to priority under 119(e) was being made as indicated by the claim for priority to a provisional application in the first sentence of the application, made at the time of the filing of the application, 4/12/01.

Response to Arguments

In the applicant's response filed 2/4/03, the applicant indicates that a compliant oath/declaration will be submitted upon receipt of the executed oath/declaration. The new oath/declaration has not yet been filed in the instant application and thus the objection to the oath/declaration remains of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-6, 9, 25-26, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new rejection necessitated by the applicant's amendment to the claims 2/4/03.

The amendment to the claims filed 2/4/03 adds the following limitation to all claims "wherein the mutation is in the transmembrane domain of the ion channel protein, and wherein the mutation does not alter the in vitro replication of the virus, but is associated with attenuation of the virus in vivo". This limitation was not present in either the claims or specification as filed and thus constitutes new matter. The applicant in the Remarks section filed 2/4/03 indicates that support for the amended claims is supported by Examples 2-3. A careful review of Examples 2-3 did not identify support because the viruses having the mutant M2 protein, including the virus having a deletion of residues 29-31 of M2 do have an alteration of the in vitro replication of the viruses as compared to wild type parent

virus: all of the M2 mutants were more resistant to amantadine than the wild type virus (page 29, lines 8-9). This is certainly an alteration of the in vitro replication of the virus because amantadine resistance is measured as an effect on in vitro replication of the virus. Neither the claims nor the specification as filed teach a virus having the properties as now claimed and thus the addition of the limitation described above to the claims constitutes adding improper new matter to the application.

Claims 1, 5-6, 9, 25-26, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new rejection necessitated by the applicant's amendment to the claims 2/4/03.

The claims are drawn to an isolated and purified recombinant influenza virus comprising a mutant (M2) protein which lacks or has reduced activity relative to the corresponding wild-type ion channel protein, wherein the mutation is in the transmembrane domain of the ion channel

protein, and wherein the mutation does not alter the in vitro replication of the virus, but is associated with attenuation of the virus in vivo. (Underlining added for instant emphasis of the portion of the claim which caused the instant rejection.)

These product claims are genus claims because they encompass influenza viruses having any mutation in the M2 protein, but which have the indicated properties. About 13 different species are specifically claimed.

However, as described in the new matter rejection set forth above, none of the species in the claims or taught by the specification have the properties as claimed because all of the described mutations increased the in vitro replication resistance to amantadine which is properly considered an alteration of the in vitro replication of the mutant viruses as compared to the wild type virus. Thus, the specification and claims do not indicate what distinguishing structural attributes are shared by the members of the genus. The specification and claims do not place any limit on the number of amino acid substitutions, deletions, insertions, and/or additions that may be made to the M2 protein transmembrane region to result in mutant viruses having the claimed properties. Thus, the scope of the claims includes numerous structural variants of the claimed products, and the genus is highly variant because a

significant number of structural differences between the genus members is permitted. Although these types of changes are routinely done in the art, the specification and claims do not provide any description as to what changes can or should be made to result in viruses having the claimed properties. Structural features that could distinguish compounds used in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common structural attributes or characteristics that identify the members of the genus, and because the members of the genus are highly variant, and especially the lack of the description of even one member of the claimed genus, clearly shows that there is insufficient description of the claimed genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant *does*

submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Terry A McKelvey

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

August 24, 2003